

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*48 SSP

Product number: 101.546-06 – including Taq polymerase
Lot number: 44K
Expiry date: 2012-September-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-625-01	9	2010-761-09
2	2006-206-02	10	2010-761-10
3	2007-336-03	11	2010-761-11
4	2009-625-04	12	2010-761-12
5	2009-625-05	13	2010-761-13
6	2010-761-06	14	2010-761-14
7	2009-625-07	15	2009-625-15
8	2009-625-08	16	2009-625-16

The specificity of each primer solution of the HLA-B*48 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6 and 8 were available. The specificities of the primers in these primer solutions were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solutions 6, 8 and 11, one or two 5'-primers were not possible to test, and in primer solution 14 two 3'-primers were not possible to test. Additional 5'-primers in primer solutions 5, 12 and 14 were tested by separately adding an additional 3'-primer, and one additional 3'-primer in primer solution 12 was tested by separately adding an additional 5'-primer.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2010-October-01

Approved by:



Quality Control, Supervisor

Lot No.: **44K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-B*48
Product number: 101.546-06
Lot number: 44K

Intended use: HLA-B*48 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
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We, Olerup SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2010-October-01



Olle Olerup
Managing Director